

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

In re.:

Heparin Products Liability Litigation

MDL No. 1953

Robert Yeazel, etc., et al.,

Plaintiff

Case No.: 1:09HC60186

v.

ORDER

Baxter Healthcare Corporation, *et al.*,

Defendants

This is a suit arising from the alleged administration of contaminated heparin, which the Judicial Panel on Multi-District Litigation has referred to the undersigned.

Pending is the plaintiff's motion to exclude the testimony of defendants' medical expert, Dr. Christopher Cooper, who opines that the death of Carol Yeazell, plaintiff's decedent, was due to heart failure and not administration of contaminated heparin. (Doc. 28). Plaintiff contends that Dr. Cooper's opinions fail to qualify for admission under Fed. R. Evid. 703 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In addition, plaintiff seeks exclusion on the basis of Fed. R. Evid. 402 and 403.

Finding that plaintiff's Rule 703 and *Daubert* objections go to weight, rather than admissibility, and finding further that the proffered testimony is relevant and not unfairly prejudicial or confusing, I overrule the motion.

Background

Mrs. Yeazel, who suffered from end stage renal disease, began hemodialysis on October 1, 2007. She routinely received heparin during her thrice-weekly four-hour sessions. Prior to the date of her death on December 23, 2007, Mrs. Yeazel had not experienced unusual or unexpected complications during hemodialysis.

On that date, Mrs. Yeazel received a bolus dose of 4000 units of heparin at 9:36 a.m. followed by a continuous maintenance dose of heparin of 500 units/hour. At 10:03 a.m., Mrs. Yeazel complained of being cold. At 11:05 a.m., Mrs. Yeazel received another bolus dose of 1000 units of heparin. At 11:05 a.m. her blood pressure was 105/60 and her heart rate was 104.¹ But she complained of "not feeling well" and was taken off dialysis circulation.

Due to the discomfort she was experiencing and episodes of vomiting and diarrhea, Mrs. Yeazel terminated the dialysis session. On returning home, she continued to experience nausea, vomiting and diarrhea. Shortly before 1:30 p.m., Mrs. Yeazel collapsed. EMS records showed pulseless electrical activity at 1:34 p.m. Never regaining consciousness, she was pronounced dead at 4:50 p.m.

According to the opinion that plaintiff's pending motion challenges, "Mrs. Yeazel died of sudden cardiac death in the setting of end-stage renal disease, a far too common public health

¹ Thirty minutes earlier Mrs. Yeazel's blood pressure was 178/81.

problem.” In his view, “[s]uggesting that heparin given four hours before her death resulted in her death seems unnecessary and unfounded, especially since review of the records does not appear to demonstrate evidence of anaphylactic or anaphylactoid reaction related to her death.”

Plaintiff challenges the admissibility of these opinions on the basis that: 1) Dr. Cooper failed to consider any scientific literature or evidence as to the effects of contaminated heparin; 2) his report contains inaccuracies and assumptions either unsupported or contradicted by the medical record; 3) his methodology is flawed; and 4) his anticipated testimony is neither reliable nor relevant.

Discussion

1. Rules 402, 403

There is no merit to plaintiff’s Rule 402 and 403 challenges to Dr. Cooper’s testimony. Testimony as to the cause of Mrs. Yeazell’s death is relevant to her claim that exposure to contaminated heparin, rather than natural causes (as Dr. Cooper concludes), was the ultimate cause. Testimony does not become irrelevant simply because it conflicts with a plaintiff’s theory of his case.

The probative value of Dr. Cooper’s opinions, if credited by the jury, is substantial. There is no risk of undue or unfair prejudice or confusing the jurors if they hear what he has to say.

2. Rule 702 and *Daubert*

Under Rule 702, opinion testimony is admissible if it will assist the trier and: 1) has an adequate factual basis; 2) is grounded in reliable principles and methods; and 3) the witness has applied the principles and methods reliably to the facts of the case.

Under *Daubert*, a trial court, as “gate-keeper,” focuses on whether the reasoning or methodology underlying the testimony is scientifically valid. *Daubert, supra*, 509 U.S. at 590. To meet this requirement, the proposed opinion must be “grounded in the methods and procedures of science and must be more than unsupported speculation or subjective belief.” *Id.*

In this case, Dr. Cooper’s methodology is entirely conventional: namely, examining the medical data and events preceding Mrs. Yeazel’s death, applying his specialized knowledge as a cardiologist to that information, and reaching and explaining his conclusions.

The issue in this case, and the one on which plaintiff focuses, is whether Dr. Cooper’s conclusions appear sufficiently reliable to allow the jury to hear them and determine whether, in light of all the other evidence, they support a verdict for the defendants.

Plaintiff challenges the reliability of Dr. Cooper’s conclusions on several grounds: 1) he failed to acknowledge, much less discuss, scientific evidence about the effects of contaminated heparin; 2) he erroneously stated that “review of the records does not appear to demonstrate evidence of anaphylactic or anaphylactoid reaction related to her death;” where, according to plaintiff, the record shows Mrs. Yeazell experience several symptoms of such reaction, including hypotension, tachycardia, nausea, vomiting and diarrhea; 3) he failed to account for and/or exclude alternative explanations of Mrs. Yeazel’s death, *i.e.*, contaminated heparin; 4) he erroneously assumed Mrs. Yeazel’s sudden cardiac death was due to left ventricular systolic dysfunction; and 4) his report contains erroneous factual information about Mrs. Yeazell’s blood pressure and misreads echocardiogram results.

To some extent, plaintiff's contentions are well taken. There is no indication in Dr. Cooper's report that he considered the published studies in reaching his conclusions.² I do not consider this to be a preclusive failing.

With regard to Dr. Cooper's conclusion about the lack of evidence of anaphylactic or anaphylactoid reaction, the parties dispute the significance of events in the medical records.³ Most importantly, with regard to the specific question of hypotension, the parties dispute the significance of the drop within thirty minutes of Mrs. Yeazell's systolic blood pressure. Such a drop, plaintiff contends, is clear (but unconsidered) evidence of heparin-induced hypotension.

Defendants contend that for Dr. Cooper what mattered was the fact that the latter reading was within a normal range. In other words, he did not consider the drop to that level to be evidence of an anaphylactic or anaphylactoid reaction.

I disagree with plaintiff that Dr. Cooper bases his finding as to the cause of death specifically on "left ventricular systolic dysfunction." Thus, plaintiff's contention in this regard does not affect the apparent reliability of Dr. Cooper's conclusions.

Finally, as I understand the dispute about the echocardiogram, the parties disagree on how those results should be read, and how accurate they likely are in the first instance. Likewise, they disagree on the medical significance of Mrs. Yeazell's heart size.

² Defendants assert in their opposition brief that Dr. Cooper in fact considered such data. No citation to the record accompanies that assertion, nor is it supported by a supplement to Dr. Cooper's report or otherwise. I take the record as it exists, not as counsel think it might exist.

³ The record of the MDL proceedings contains considerable evidence that hypotension, nausea, diarrhea and vomiting are common side-effects during dialysis. I do not find that Dr. Cooper's failure to acknowledge this in his report undercuts its reliability to such an extent that he cannot testify.

These disagreements do not make Dr. Cooper's report *ipso facto* unreliable.

Instead of justifying preclusion of Dr. Cooper's testimony and opinions, plaintiff's objections and challenges to its reliability go to weight, not admissibility.

Conclusion

For the foregoing reasons, I find no basis for excluding Dr. Cooper's testimony about the cause of Mrs. Yeazell's death (and the lack of any causal connection between her death and contaminated heparin).

It is, therefore

ORDERED THAT plaintiff's motion to exclude the testimony of Dr. Christopher Cooper be, and the same is overruled.

So ordered.

/s/ James G. Carr
Sr. United States District Judge